

**COMPLETE ALLERGY AND SINUS MULTI SYMPTOM- acetaminophen, chlorpheniramine maleate and phenylephrine hcl tablet, film coated  
GREAT LAKES WHOLESAL, MARKETING, & SALES, INC.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Healthcare 44-455C-Delisted**

***Active ingredients (in each caplet)***

Acetaminophen 325 mg  
Chlorpheniramine maleate 2 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever  
Antihistamine  
Nasal decongestant

***Uses***

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
  - headache
  - nasal congestion
  - runny nose and sneezing
  - minor aches and pains
  - sinus congestion and pressure
- temporarily relieves these additional symptoms of hay fever:
  - itchy, watery eyes
  - itching of the nose or throat
- helps clear nasal passages
- helps decongest sinus openings and passages

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if you have**

- difficulty in urination due to enlargement of the prostate gland
- glaucoma
- high blood pressure
- a breathing problem such as emphysema or chronic bronchitis
- heart disease
- thyroid disease
- diabetes
- liver disease

### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- drowsiness may occur

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present

These could be signs of a serious condition.

### **If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

***Directions***

- **do not take more than directed**
- adults and children 12 years and over
  - take 2 caplets every 4 hours
  - swallow whole - do not crush, chew, or dissolve
  - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

***Questions or comments?***

**Call 1-800-426-9391**

**Principal Display Panel**

**HEALTHCARE™**

NDC 64092-865-24

**Complete**

**Allergy & Sinus**

Multi-Symptom CAPLETS

**Acetaminophen 325 mg,**

*Chlorpheniramine maleate 2 mg,*

*Phenylephrine HCl 5 mg*

*Pain Reliever, Antihistamine,*

*Nasal Decongestant*

**Relieves:**

- **Headache • Sinus Pressure**
- **Nasal Congestion • Runny Nose**
- **Sneezing • Itchy, Watery Eyes**

Pseudoephedrine FREE

**24 COOL CAPLETS**  
with Cool Blast Flavor

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED  
OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS  
ANY SIGNS OF TAMPERING**

50844 REV0818G45508

Distributed by:  
Great Lakes Wholesale & Marketing L.L.C.  
3729 Patterson Ave., S.E.  
Grand Rapids, MI 49512 [www.glwholesale.com](http://www.glwholesale.com)

**HEALTH CARE GUARANTEE**

**If you are not completely satisfied with this product, regardless of reason, return your unused portion to Great Lakes Wholesale for a full refund**

<p><b>(in each caplet)</b> Acetaminophen 325 mg .....Pain reliever Chlorpheniramine maleate 2 mg .....Antihistamine Pseudoephedrine HCl 5 mg .....Nasal decongestant</p> <p>■ headache ■ nasal congestion ■ minor aches and pains ■ runny nose and sneezing</p>	<p><b>Drug Facts (continued)</b></p> <p>■ temporarily relieves these additional symptoms of hay fever: ■ itchy, watery eyes ■ itching of the nose or throat ■ helps clear nasal passages ■ helps decongest sinus openings and passages</p> <p><b>Warnings</b> Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ rash ■ skin reddening ■ blisters ■ If a skin reaction occurs, stop use and seek medical help right away. <b>Do not use</b> ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. ■ if you have ever had an allergic reaction to this product or any of its ingredients <b>Ask a doctor before use if you have</b> ■ glaucoma ■ difficulty in urination due to enlargement of the prostate gland ■ high blood pressure</p> <p><b>Drug Facts (continued)</b></p> <p>■ a breathing problem such as emphysema or chronic bronchitis ■ heart disease ■ thyroid disease ■ diabetes ■ liver disease <b>Ask a doctor or pharmacist before use if you are</b> ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers <b>When using this product</b> ■ do not exceed recommended dosage ■ excitability may occur, especially in children ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic beverages ■ use caution when driving a motor vehicle or operating machinery ■ drowsiness may occur <b>Stop use and ask a doctor if</b> ■ nervousness, dizziness, or sleepiness occur ■ pain or nasal congestion gets worse or lasts more than 7 days ■ new symptoms occur ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ These could be signs of a serious condition. <b>If pregnant or breast-feeding, ask a health professional before use.</b> <b>Keep out of reach of children.</b> In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. <b>Directions</b> ■ do not take more than directed ■ adults and children 12 years and over ■ take 2 caplets every 4 hours ■ swallow whole - do not crush, chew, or dissolve ■ do not take more than 10 caplets in 24 hours ■ children under 12 years: ask a doctor</p>
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B-0616-455  
REV0818



**Healthcare 44-455C-AMS**

**COMPLETE ALLERGY AND SINUS MULTI SYMPTOM**

acetaminophen, chlorpheniramine maleate and phenylephrine hcl tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64092-865
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE -	CHLORPHENIRAMINE	

UNII:3U6IO1965U)	MALEATE	2 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	44;455
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-865-24	2 in 1 CARTON	06/28/2005	07/25/2024
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/28/2005	07/25/2024

**Labeler** - GREAT LAKES WHOLESAL, MARKETING, & SALES, INC. (361925498)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(64092-865)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(64092-865)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(64092-865)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(64092-865)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(64092-865)

Revised: 9/2023

GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.